

REMARKS

I. INTRODUCTION

The final Office Action mailed on June 9, 2005 and the publications cited therein have been carefully studied and, in view of the following representations, reconsideration and allowance of this application are most respectfully requested.

Upon entry of the present amendment, claims 51-64 will be pending in the present application. By the present amendment, claims 1, 4, 7-9, 12, 39 and 41-50 have been cancelled without prejudice, and new claims 51-64 have been added. No new matter has been added herein by the present amendment, as support thereof can be found in the specification at, *inter alia*, page 7, lines 11-13 and 19; page 8, lines 3-4; page 9, lines 14-15; page 10, line 24 to page 11, line 6; page 12, lines 28-30; and page 22, line 9. In view of the foregoing amendments and the following remarks, Applicants respectfully submit that the claims are now in condition for allowance. Applicants point out that the amendments made herein are made without prejudice to the future prosecution of such cancelled, amended or modified subject matter in a related divisional, continuation or continuation-in-part application.

II. REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1, 4, 7-9, 12, 39 and 41-50 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. As these claims have been

cancelled herein without prejudice, Applicants respectfully submit that these claim rejections have been rendered moot and should therefore be withdrawn.

New claims numbered 51-56 and 63 include the claim recitation of “wherein the mammal is asymptomatic to lung damage or wherein the clinical diagnosis of lung damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures.” Similarly, claims 57-62 and 64 include the claim recitation of “wherein the mammal is asymptomatic to alveolo-capillary membrane damage or wherein the clinical diagnosis of alveolo-capillary membrane damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures.” Support for such claim language can be found in the specification at, *inter alia*, page 22, line 9; page 9, lines 14-15; and page 12, lines 28-30. Applicants respectfully submit that such claim language is definite in accordance with 35 U.S.C. § 112, second paragraph.

III. REJECTIONS UNDER 35 U.S.C. § 102(b)

Claims 1, 4, 7-9, 12, 39 and 41-50 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Doyle et al. (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10/18/00). As these claims have been cancelled herein without prejudice, Applicants respectfully submit that these claim rejections have been rendered moot and should therefore be withdrawn.

To anticipate a claim, a reference must disclose each and every element of the claimed invention. *Verdergaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 2 USPQ2d

1051 (Fed. Cir. 1987). In regard to the new claims, Applicants respectfully submit that Doyle et al. does not disclose or suggest each and every element of these claims.

As previously described, new claims numbered 51-56 and 63 include the claim recitation of “wherein the mammal is asymptomatic to lung damage or wherein the clinical diagnosis of lung damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures,” and new claims 57-62 and 64 include the claim recitation of “wherein the mammal is asymptomatic to alveolo-capillary membrane damage or wherein the clinical diagnosis of alveolo-capillary membrane damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures.” In that regard, we note that neither such mammal group is expressly or inherently disclosed in Doyle et al. That is, Doyle et al. does not disclose or suggest that the members of the control group (*i.e.*, normal individuals) or OD group (*i.e.*, ventilated patients with no evidence of cardiorespiratory disease) are necessarily “asymptomatic to” lung damage or alveolo-capillary membrane damage, or that the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the mammal “cannot otherwise be confirmed without the aid of one or more invasive procedures.” The only meaningful, distinguishing characteristic of the individuals in the Doyle et al. control or OD groups is that they are not placeable in the diseased groups (*i.e.*, they do not have the specific conditions APE or ARDS). In addition, Doyle et al. only discloses that elevated SP-B levels accompany diseased patients afflicted with APE or ARDS.

IV. REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 8, 9, 12, 39 and 44-50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Honda (Japanese Journal of Thoracic Diseases, 34 Suppl Abstract only,

December 1996; reference A11 on PTOL-1449 of 6/6/00) in view of Doyle et al. and Abe et al. (Japanese Journal of Thoracic Diseases, 33(11):1219, Abstract only, November 1995; reference A10 on PTOL-1449 of 6/6/00). As these claims have been cancelled herein without prejudice, Applicants respectfully submit that these claim rejections have been rendered moot and should therefore be withdrawn.

In order for a claim to be rejected for obviousness under 35 U.S.C. § 103(a), not only must the prior art teach or suggest each element of the claim, but the prior art must also suggest combining the elements in the manner contemplated by the claim. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F. 2d 931, 934 (Fed. Cir. 1990), *cert. denied* 111 S.Ct. 296 (1990); *In re Bond*, 910 F. 2d 831, 834 (Fed. Cir. 1990). The Examiner bears the initial burden of establishing a *prima facie* case of obviousness. *See* M.P.E.P. §2142. To establish a *prima facie* case of obviousness, the Examiner must show, *inter alia*, that there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references and that, when so modified or combined, the prior art teaches or suggests all of the claim limitations. *See* M.P.E.P. §2143.

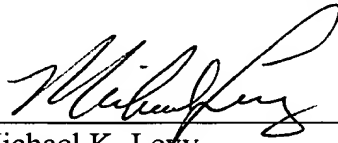
In regard to the new claims numbered 51-64, Applicants respectfully submit that these claims are not rendered obvious over Honda in view of Doyle et al. and Abe et al. That is, neither Honda or Abe et al. cure the shortcomings of Doyle et al. as described above in relation to the anticipation rejections.

V. CONCLUSION

In light of the foregoing, Applicants respectfully submit that all pending claims are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,
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